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Minutes June 14, 2000 UN-Third Party Certification Agencies/Public Meeting Bloomingdale, Illinois

The Research and Special Program Administration's (RSPA) Office of Hazardous Materials Safety (OHMS) held a public meeting on June 14, 2000, with the approved United Nations Third Party Certification Agencies. These are the third party labs RSPA has inspected and approved to conduct UN testing and to certify non-bulk packagings in accordance with the Hazardous Materials Regulations (HMR). Meetings are held between RSPA and the approved third-party labs to provide an exchange of information and to provide an opportunity to discuss testing requirements regarding performance-oriented packaging.

In addition RSPA published a Federal Register Notice inviting other interested parties to the meeting. The meeting was held in conjunction with the two-day Multi-Modal Hazardous Materials Seminar. The meeting was attended by approximately 80 people who represented testing labs, packaging manufacturers, shippers, industry consultants and publishers.

Mr. Ed Mazzullo of the Office of Hazardous Materials Standards opened the meeting, welcomed the participants and introduced members of the panel and the enforcement personnel who represented the field offices. He encouraged open discussions on all matters, especially the draft question and answers that were distributed. Mr. James Jones moderated the meeting and pointed out that this was the first time the meeting was held outside of Washington, D.C. The participants were asked to provide their opinions regarding this change of venue.

Approvals Office Overview

Ms. Christine Whitney of the Approvals office discussed changes and updates regarding the Third-Party Certification Program. The labs were informed that many of the third-party documents are now located on the Office of Hazardous Materials Safety's web site at http://hazmat.dot.gov. They were asked to

to the listing. Also, the labs were advised that they can provide their e-mail addresses to be included on the third-party listing if they wish.

The labs were then asked to review their approval letters to ensure that they are fulfilling their responsibilities, especially with respect to notifying DOT of any changes in personnel or lab capabilities. They were also reminded that they must have on file copies of all documents provided to the Approvals Office. Failure to produce the required documents to a DOT enforcement representative during an inspection is considered a violation.

Third-Party Certification Agencies Are Now Required to Pay for an Approval Inspection

Ms. Whitney explained that on October 27, 1997, Public Law 105-66 established that "RSPA shall collect fees for expenses necessary to discharge the functions of the RSPA . . . and for travel expenses incurred in performance of hazardous materials exemptions and approvals functions." All new labs and those labs that are required to be re-inspected must bear the expense of the inspection. RSPA has approved one lab since these new procedures have gone into effect.

Termination of the first Third-Party Lab

The first third-party lab was terminated in 1999. The attendees were advised that an approved third-party lab could be terminated due to violations of the regulations and/or violations of their approval letter. The attendees were then informed that as a result of termination proceedings against the lab, a committee was formed to establish show-cause criteria to be used in any termination of an approval. This topic was later discussed by a representative of RSPA's Office of the Chief Counsel.

Internet Availability

Dr. Richard Tarr of the Exemptions and Approvals Office provided a description and overview of the OHMS's web site. He explained how to access the exemptions and approvals documents and listed the latest information available that would be of particular interest to the audience including: Questions and Answers for years 2000, 1998, 1995, 1992, and 1990; Meeting Minutes for years 1997, 1994, and 1992; Other Documents; Application Procedures, and Show-Cause Criteria. He also discussed additional information that will be included in the near future.

Show-Cause Criteria

Mr. Robert Monniere of the Office of the Chief Counsel explained RSPA's new show-cause criteria. He noted that 49 CFR Part 107 contains broad guidelines for termination, modification, or suspension of approvals. The new "show-cause" guidelines are in a document meant to help RSPA and approval holders understand how RSPA will handle a situation where an approval holder is no longer able or willing to fulfill the conditions of the approval. These procedures apply not only to third party lab approvals but to all approvals issued by RSPA. Mr. Monniere indicated that RSPA does not intend to incorporate the show-cause criteria into Part 107.

Generally, RSPA will consider terminating an approval where problems with the approval holder have been identified and confirmed by an enforcement inspector. RSPA has identified three basic criteria for determining if an approval termination proceeding is necessary. Generally, at least one of three criteria must be met before RSPA would consider terminating an approval. The first is the capability of the approval holder (person or entity) to perform the duties or other requirements of the approval. RSPA would consider termination of the approval if they felt it necessary "to prevent continued non-compliance or additional violations of the regulations (e.g., lack of properly trained staff or lack of proper testing equipment)."

The second consideration is the seriousness of the approval holder's violation. If RSPA finds a "strong probability that continued violations could cause serious physical or economic hardship to the public," termination proceedings will be considered. Finally, RSPA will consider "evidence that a company or a company's officials have sufficient current and prior violations to reflect a disregard for, or intent to not comply with, the regulations."

After evaluating these factors, the inspector and his or her unit chief will decide whether or not to initiate a show-cause proceeding. If they decide to go forward, a show-cause letter is drafted and reviewed by the Office of Hazardous Materials Enforcement, and then by the Office of Hazardous Materials Exemptions and Approvals, the Office of Hazardous Materials Technology, and the Office of the Chief Counsel. The letter asks the approval holder to show cause why the approval should not be terminated or suspended, and the approval holder is given the opportunity to address RSPA's concerns.

RSPA indicated that show-cause proceedings are separate from

enforcement proceedings, but where a Notice of Probable Violation is appropriate, they will try to issue the Notice of Probable Violation at the same time as the show-cause letter. Where there are potential criminal prosecutions involved (where a willful violation of the regulations has occurred), RSPA will work with the Department of Justice.

The entire show-cause document was distributed and, as stated earlier in this document, is available on RSPA's web site.

Technical Update

Mr. Don Burger of the Hazardous Materials Technical Office discussed several technical issues including the currently perceived problems with performance-oriented packaging (POP), non-specification "Rigid Bag" packaging, closing instructions, test documentation, stacking tests for non-bulk packages and the top-lift test for flexible IBCs.

Perceived problems with UN performance packaging.

After the transition to UN POP packaging there has been an alleged increase in the number of reported hazardous materials incidents (especially in transportation by air). This has lead to a concern by some groups that the new packaging has not performed as well as the old DOT specification packaging. Mr. Burger pointed out that the increased number of reported incidents does not necessarily mean there are problems with UN packaging. He said that DOT's increased emphasis on reporting means more incidents are reported, and the increased number of incidents may be partly attributable to an increased number of shipments. Preliminary research indicates one of the most frequent problems is leaking combination packaging.

He stated that DOT will investigate what needs to be done to address the air-worthiness of inner packagings of combination packages. This may include specific test requirements for the packages as well as a package marking to indicate the package has been tested to the appropriate pressure differential for air transport.

He asked that the labs pay close attention to the closing procedures that are provided with the packagings to make sure that there is sufficient detail to ensure a secure, repeatable closure on all packages. Bob Richard added that RSPA had submitted a proposal to the UN Sub-Committee of Experts proposing that manufacturers and down-stream distributors provide closure instructions to users of non-bulk packagings and IBCs. He noted

that a review of the HMIRS database showed a high incidence of closure failures relative to packaging releases.

Non-Specification "Rigid Bag" Packagings

Mr. Burger explained that there has been an increase in the use of rigid-bag style packagings. These packages have multi-wall, woven fabric outer layers that sandwich up to six layers of corrugated board. The corrugated board provides structural integrity to the package. The outer packagings utilize a plastic inner bag as a receptacle for the material being transported.

The question was posed to the group asking if they have seen these types of packagings and, if so, how did they classify them? There was no consensus as comments ranged from a flexible IBC to a composite IBC based upon the structural integrity provided by the fiberboard.

DOT has currently interpreted one of the bulk size packagings, with six layers of wall board, to be a composite IBC. The decision to mark it as a composite IBC must be made by the manufacturer based upon whether the usage scenario meets the definition of "composite" provided in §178.707(b)(1)(i.e., if the inner receptacle and the inner packaging form an integral packaging and are filled, stored, transported and emptied as a unit). The non-bulk packagings are generally considered to be bags based upon the definitions in the HMR.

Closing Instructions and Test Documentation

Again, Mr. Burger told the meeting participants to pay close attention to closing procedures when testing packagings and documenting the tests. Mr. Jones noted that the test lab must tell the packaging user what it takes to close a package adequately for shipment. This brought about a great deal of discussion over what exactly should be in a test report and what the test lab's responsibility is.

A lab representative noted that testing in the lab occurs under certain conditions of temperature, pressure, and dwell time, and the conditions in the lab do not replicate conditions under which the packagings are actually filled. RSPA responded that if the packaging user is loading and closing a packaging under different conditions than those under which the packaging was tested, they are outside the certification issued by the lab. A lab representative asked who determines what is to be shown on a test

report with regard to the closure of a 4G box. RSPA responded that the tester and the ultimate user of the packaging should get together and determine how the package will be closed. The person responsible for the package certification needs to determine how it will be closed and test it accordingly. Bob Richard noted that the lab's customer (the shipper or manufacturer) should tell the lab how the package will be closed for shipment.

RSPA again stressed the importance of complete test documentation, as it has consistently done for years. Don Burger noted that 49 CFR 178.601(1) identifies what is required in a test report. However, RSPA finds it difficult to track down information from test reports, and is asking for an industry effort to standardize test reports. RSPA will not dictate a test report format or detailed content. Ed Mazzullo noted that the test report is used to verify compliance with regulatory requirements, and Doug Smith noted that the primary way to determine compliance is by comparing a packaging to the test report. The labs were told that it was in their best interest to have test reports as complete as possible. Thus, if there is a packaging failure, RSPA can determine whether someone made a modification change to the packaging thereby nullifying the certification.

A lab representative asked whether RSPA has consistently noticed specific information missing from test reports. In response, RSPA noted that conditioning requirements, especially for 4G boxes, are frequently not included in the test report. Further, RSPA noted that often the general packaging description is too vague to adequately identify what was tested. Labs were urged to make sure they describe the packaging to the greatest extent possible.

International standards. Assistant International Standards Coordinator Bob Richard highlighted recent United Nations' activities. He urged the labs to play an active role in the activities of the UN Committee of Experts on the Transport of Dangerous Goods (COE) and stressed that "What's adopted at the UN usually ends up in the US regulations." He informed the participants about ways they could participate in the work and highlighted information provided on the RSPA web site including a link to the UN papers and summaries of decisions taken at UN meetings.

He provided information on some of the key issues being considered by the COE. He solicited comments on several packaging papers submitted to the eighteenth session of the Sub-

Committee of Experts on the Transport of Dangerous Goods (SCOE). He noted that there is some interest in adding a vibration test to the UN standards, as well as a puncture resistance test, though nothing specific has been proposed with regard to puncture resistance. Further, he pointed out that work continues on the development of a CEN/ISO standard for detailed non-bulk package and IBC testing procedures, and once those procedures are adopted as an ISO standard, they could potentially be proposed for incorporation into the UN Model Regulations. He noted that draft standard ISO/DIS 16104 (Transport Packaging for Dangerous Goods' Test Methods) was close to being adopted and that the following drafts were also close to being finalized: (1) ISO/DIS 13355 (Complete Filled Transport Packages and Unit Loads; Vertical Random Vibrations); (2) ISO/DIS 16101 (Transport Packages for Dangerous Goods - Plastic Compatibility Testing); and (3) ISO/DIS 16407 (Transport Packages for Dangerous Goods - Test Methods for IBCs).

He stated that while these standards include requirements consistent with the UN Recommendations in many instances they provided more detailed requirements which should be carefully reviewed by the labs and they were urged to take an active role in the development of the ISO standard. He suggested that the packaging test labs attempt to provide coordinated feedback to RSPA on international issues relevant to the testing of hazardous materials packagings. When asked a question regarding the US position concerning self-certification, he indicated that the U.S. intends to maintain its current system of allowing self-certification, and that RSPA does not interpret the ISO standard on hazmat package testing to mandate third party testing and certification.

RSPA Enforcement

Mr. Doug Smith of RSPA's Office of Hazardous Materials Enforcement provided an overview of the enforcement process and commented on recent enforcement issues. As many of the lab representatives in attendance had not previously attended one of DOT's third party lab meetings, Mr. Smith presented a brief description of what the labs can expect during a RSPA enforcement inspection. He emphasized that all inspections are unannounced. Generally, the inspector will request a copy of the annual report of package testing that each lab must submit to RSPA. At the beginning of an inspection, the RSPA inspector will discuss, with a company representative that is familiar with UN testing, the company's corporate structure, types of packagings tested, and the approval letter.

The RSPA inspector also looks at the company's test equipment and assesses the lab's ability to perform the required tests. For example, the inspector examines the conditioning equipment and data recording devices and then checks the equipment calibration. The RSPA inspector will usually observe some actual testing. Finally, sample test reports will be reviewed, as well as hazmat employee training records.

At the conclusion of the inspection, the RSPA inspector will complete an exit briefing before leaving the third party-lab facility. Noted violations and possible sanctions will be discussed with the company representative. The consequences of an RSPA inspection can include a warning letter, a "ticket" or a Notice of Probable Violation (NOPV). A ticket is the lowest level of violation issued by RSPA, and is issued for violations of the Hazardous Materials Regulations with minor safety implications. Issuance of a ticket rather than an NOPV speeds the enforcement process and results in a lower penalty amount than the standard civil penalty process.

He noted that for more serious violations, such as a test lab using the wrong drop height or wrong number of samples, or performing incomplete testing, improperly certifying packagings or failing to maintain complete test records, a civil penalty action will in all probability ensue. The civil penalty action could also result in the preparation of a show-cause letter, which could lead to a proceeding to terminate the lab's approval as a third party packaging certification agency.

Mr. Smith provided some statistics on the numbers of enforcement actions that have been brought against the third party certification agencies. He said that to date, 29 enforcement actions have been taken against the third party labs. Two of those actions were dropped, but he expressed the feeling that 27 enforcement actions is a fairly significant number, given the relatively small number of inspections of these facilities that takes place. From January 1999 to June 2000, RSPA performed over 3000 inspections of all types. Of those 3000 inspections, only 14 were of third party labs. From those 14 inspections, 4 civil penalty actions, 1 ticket, and 1 warning letter resulted.

While acknowledging that "mistakes are made," he emphasized that DOT expects more of the approved third party labs than of self-certifiers.

<u>Tobyhanna</u>. Giving an update on the package testing taking place at Tobyhanna, Pennsylvania, Mr. Smith discussed the relatively high failure rates. He explained that RSPA typically buys

packagings in lots of 24. If a single packaging fails, RSPA considers that a design failure, but that does not necessarily mean an enforcement action will be initiated. Tobyhanna will conduct additional tests in the same failure mode. He noted that most of the packagings tested at Tobyhanna have been self-certified, but RSPA has purchased third party certified packagings that failed. When that happens, RSPA will check to make sure the packagings Tobyhanna tested are the same as those originally sent to the third party lab for testing. If the manufacturer changed the packaging after testing, that is not the third party lab's responsibility.

As a result of the testing at Tobyhanna, RSPA has initiated 42 enforcement cases, 25 of which have been closed, with \$138,000 in fines collected. He added the testing is "getting the attention" of industry and has allowed RSPA to identify problems they wouldn't have before. Several testing issues brought to light recently include:

- · Some companies have argued that dropping on steel is more severe than dropping on concrete. Mr. Smith noted that if the concrete surface is set up properly, there should be no discernable difference between steel and concrete. The concrete drop surface must be thick enough to have 50 times the mass of the heaviest packages dropped on it.
- Some labs are not cold conditioning their plastic packagings long enough. Mr. Smith noted that it takes almost 72 hours to get a 55-gallon drum and its contents to the correct temperature, and plastic drums put in a conditioning chamber just overnight are likely not at the required 0°C temperature when tested.
- During the drop test, the center of gravity of the package being tested must be vertically over the point of impact in the drop. The difficulty is in trying to find something to hold the packaging to ensure the center of gravity is over the point of impact and which won't affect the closure or cause the package to rotate as it is dropped.
- RSPA has purchased from distributors open head drums with the covers in place, with no bung openings. To fill the drums, RSPA/Tobyhanna has encountered difficulty in pulling the covers off without damaging the gasket. An actual purchaser of such drums would have the same difficulty removing the cover and getting it back on and seated properly on the gasket.

- RSPA is still evaluating whether vibration testing of IBCs can be performed with water as opposed to a material with a specific gravity similar to that which will be transported in the IBC.
- With regard to information on test reports, Mr. Smith emphasized that "more is better."

One of the lab representatives wanted to know whether, to stay out of trouble, the test labs need to "mirror" the testing being done at Tobyhanna, and need to try to test the "worst case" packaging that has been sitting around awhile. Ed Mazzullo pointed out the regulatory requirement that every packaging, anywhere in the system, has to be capable of withstanding the test requirements. If a packaging sitting in the warehouse 6 months results in degradation of that package, the shipper and the manufacturer should explore that possibility before testing. Doug Smith pointed out that testing packagings that have been stored is a realistic test, since distributors are routinely storing packagings these amounts of time.

Meeting attendee Howard Skolnik acknowledged that packaging performance does diminish with age, but the regulations don't place limits on how long a test is effective. Since Tobyhanna testing has found that with time, package performance diminishes, Skolnik wondered whether tests should be performed within a specific time.

Questions and Answers

The afternoon session of the third party lab meeting was devoted to discussing 31 questions posed by the third party labs before the meeting, and the answers prepared by RSPA. RSPA handed out "draft" responses to the questions, and emphasized that their responses may change as a result of discussions and the exchange of views that took place at the meeting. Therefore, the following should not be considered official RSPA positions. The final questions and answers document will be issued at a later date.

"Composite" vs. "combination" packaging. RSPA reiterated that a packaging consisting of an outer fiberboard box with an inner plastic bag should be considered either a combination packaging (if the inner packaging is removed from the outer packaging for emptying) or a composite packaging (if the inner and outer packagings remain an integrated single unit for emptying), depending on how it is used. A test lab is not obligated to anticipate every possible use of a packaging, but should ask their customer for whatever information they need. If a packaging is intended to be used either way - combination or composite - the most severe tests should be conducted and the packaging should be qualified for use both as a UN 6HG2 and a UN4G.

- · Internal pressure capability requirement for air shipments. RSPA discussed the requirement in 49 CFR 173.27(c) that packagings shipped by air be capable of withstanding a specified internal pressure, to ensure they will not leak when the pressure outside the packaging drops at high altitude. RSPA pointed out that a specific test is not required - air pressure or hydrostatic pressure may be used. conducted by subjecting the outside of the packaging to a vacuum could be used, but RSPA made clear that such a test is not an acceptable method of complying with 49 CFR 173.27(c) for flexible packagings such as plastic bags. RSPA indicated that a vacuum test on a flexible packaging was not appropriate because the packaging would stretch to compensate for the pressure differential and because this test would not take into account the vapor pressure of the content (e.g., a Class 3 flammable liquid such as isopropyl alcohol). Despite some arguments from the lab representatives that the vacuum test most closely approximates the conditions that will occur during transportation, RSPA believes that the vacuum test is inappropriate for flexible packagings that will expand to compensate for the decrease in pressure outside the packaging.
- Medical waste packagings. In response to a lab's question, RSPA confirmed that a particular puncture test is not specified for medical waste packaging covered by 49 CFR 173.197. A lab representative noted that some ASTM draft standards cover puncture resistance for sharps containers. RSPA stated that they were considering ASTM standards applicable for puncture resistance and propagation tear resistance for medical waste packagings.
- · Use of U.S. third party marks on packagings manufactured in foreign countries. In responding to a question posed by a lab before the meeting, RSPA stated that a U.S. third party lab may test a packaging manufactured in a foreign country. If the foreign country's competent authority approves the use of the U.S. third party lab symbol the packaging may be marked with the "+" designation. RSPA restated its position that any packaging assembled and marked in the USA, regardless of where the components were actually made, can be marked "USA." Where the packaging is marked determines where it is "manufactured." Bob Richard noted that the Mexican government has not yet

established a means for applying the "MEX" mark to packages but that progress has been made and that this issue should be resolved soon.

- · Packagings "liable to be reconditioned." For the first time, RSPA indicated that any drum that meets the minimum thickness requirements for reuse in 49 CFR 173.28 should be considered "liable to undergo a reconditioning process." Such drums must be marked in a permanent manner. RSPA does not believe that embossing is the only permanent [marking] form which is able to withstand the reconditioning process. Other means of marking such as attachment of a plate could satisfy this requirement.
- · Continued use of third party mark on packages. In response to a question posed by a lab before the meeting, RSPA originally stated that a manufacturer whose packagings were tested by a third party lab, but were tested by a different lab for the periodic design requalification, may continue to use the marking of the original third party lab on any packagings manufactured after the design requalification. RSPA said that the periodic recertification may be performed by the original third party lab, another designated or non-designated lab, or by the packaging manufacturer. Many of the lab representatives took exception to RSPA's position, noting that it is a mistake and misleading to let someone else use a third party lab's mark when that lab has no control over the package retesting. The third party symbol should only be used when that third party lab did the work. RSPA pointed out that the third party labs can include a provision in their contracts with customers that states the customer can't continue to use the third party mark unless that third party lab conducts the testing. There was a lengthy and lively debate of this issue and it is possible RSPA will reevaluate its position.
- · Vibration test for IBCs. RSPA has been struggling to decide whether the vibration test for IBCs may be conducted using water as a test medium rather than using a test medium that more closely represents the hazardous material to be shipped. RSPA pointed out that the regulations say that IBCs must be tested in a way that represents the hazardous material being shipped, and do not provide for the use of water for testing. Using a non-hazardous material for testing, test labs can only get up to about 1.5 specific gravity. Adding sand adds weight but doesn't replicate what you'd experience with an IBC filled with a heavy liquid. DOT understands the concerns and is working with RIBCA and Ten-E Packaging to determine what is the best way to resolve this issue. Results of testing so far

show that water gives at least as severe a test as testing with a sand/water combination. (Water is routinely used in vibration testing of non-bulk packagings because the vibration standard is a capability requirement rather than a required test.)

- Drop test orientation for drums. RSPA discussed the proper drop orientation for drums. A lab had asked whether each drum should be in the same position for testing, or if the drum could be rotated in each of the three drops to test different locations. RSPA pointed out that the second drop (using three samples) must be on the weakest point not tested in the first drop. RSPA reiterated that all three drops must be on the same, weakest spot. In some cases the tester must do several drops to determine the most vulnerable spot. These are considered "investigative" drop tests. Once the weakest spot is determined, three samples must be dropped in that orientation.
- Vented closures. RSPA said that while pressure relief devices may be removed from an IBC for testing, the same is not true for vented closures of non-bulk packagings. RSPA's reasoning is that the pressure relief device on an IBC is usually in the vapor space, and the IBC generally remains in an upright position. Non-bulk packagings are not always in an upright position.
- · "Different packaging." As is the case at each third party lab meeting RSPA has conducted, there was a lengthy discussion of what constitutes a change to a packaging requiring additional design qualification testing. In particular, labs wanted to know whether box manufacturers and/or corrugated board suppliers could be changed without the need for additional design qualification testing. RSPA stood by its assertion that to be considered the same design type packaging, a new packaging must be "virtually identical" to the tested packaging, down to board combinations and the fiberboard's ability to withstand the Cobb test. Labs noted that their customers frequently do not include specific information about the fiberboard when presenting packagings for testing. Without such information it would be difficult for another manufacturer to reproduce the box. Again RSPA emphasized the importance of thorough documentation.